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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/559,764	04/27/2000	Hans Jakob Flodgaard	5694.200-US	2707

23650 7590 04/11/2005

NOVO NORDISK, INC.
PATENT DEPARTMENT
100 COLLEGE ROAD WEST
PRINCETON, NJ 08540

EXAMINER

OUSPENSKI, ILIA I

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/559,764

Applicant(s)

FLODGAARD ET AL.

Examiner

ILIA OUSPENSKI

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-11, 15-42 and 53-60 is/are pending in the application.
- 4a) Of the above claim(s) 7-11 and 15-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 02/09/2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of this application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Ilia Ouspenski, Group Art Unit 1644, Technology Center 1600.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/09/2005 has been entered.

3. Claims 7 – 11, 15 – 42, and 53 – 60 are pending.

Claims 7 – 11 and 15 – 42 have been withdrawn from further consideration as being drawn to nonelected inventions.

Claims 53 – 60 are under consideration in the instant application.

4. This Office Action will be in response to applicant's arguments, filed 02/09/2005.

The rejections of record can be found in the previous Office Action, mailed 11/03/2003.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.

It is noted that New Grounds of Rejection are set forth herein.

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5. Applicant's IDS, filed 02/09/2005, is acknowledged, and has been considered. However, the reference has been lined through as it is not appropriate for printing on the face of the Patent.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

7. Claims 53 – 55 and 60 stand rejected under **35 U.S.C. 102(e)** as being anticipated by Oppenheim et al. (US Patent No. 5,837,247; of record, see entire document), as evidenced by Rasmussen et al. (FEBS Letters, 1996, 390: 109 – 112; of record, see entire document).

Given the absence of additional rebuttal to the outstanding rejections of record (mailed 11/03/2003) in applicant's amendment (filed 02/09/2005), the rejection is maintained for the reasons of record.

The rejection of record is incorporated by reference herein as if reiterated in full.

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8. Claims 53 – 60 are rejected under **35 U.S.C. § 102(f)** because the applicants did not invent the claimed subject matter.

Applicant's Communication, filed 02/09/2005, discloses a Complaint filed against the assignee of this application in U.S. District Court for the Northern District of Georgia, alleging that the inventors listed on the publication of this application are incorrect. Applicant notes that the Complaint has never been served on applicant or assignee and that therefore, no litigation is pending.

This Communication further indicates that applicant believes that this allegation is without merit and the correct inventors have been named. In turn, applicant asserts that the Complaint does not constitute any impediment to allowance of the present claims.

However, according to the Complaint (see Sections 14-15), the patentable matter described in each of the referenced patent applications, including the instant application, has been drawn from the original research of Narinder Gautam, as reported in his thesis entitled: "Mechanism for Leukocyte-Mediated Adjustment of Endothelial Barrier Function".

The Complaint is consistent with the generally accepted principle that a doctoral candidate must exhibit original and independent research as evidenced by their thesis to fulfill the requirements for the degree of Ph.D. The thesis is published only under the name of Narinder Gautam, who must be presumed to be largely responsible for the work obtained therein. Furthermore, the doctoral research by Narinder Gautam appears to be related to the instantly claimed subject matter, as evidenced e.g. by the last sentence in the Abstract of the thesis: "These data suggest a novel pathway involving the contact system by which activated PMN, via the release of HBP, act to regulate the endothelial barrier function at sites of inflammation."

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Because of this ambiguity, it is incumbent on applicants to provide a satisfactory showing which would lead to a reasonable conclusion that applicants Flodgaard, Lindbom and Bjorn alone are the inventors of the claimed invention. To resolve the ambiguity, applicants may file a declaration by the non-applicant Narinder Gautam, who appears to have conceived and conducted the claimed subject matter in the thesis, entitled "Mechanism for Leukocyte-Mediated Adjustment of Endothelial Barrier Function".

Furthermore, applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonable necessary to the examination of this application:

(1) A complete copy of the Narinder Gautam's Thesis entitled: "Mechanism for Leukocyte-Mediated Adjustment of Endothelial Barrier Function", including a verified English translation, if it is not in English.

(2) Any publications by Narinder Gautam, published before or after the priority date of the instant application, including abstracts and proceedings of conference presentations, that relate to the instantly claimed subject matter.

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained will be accepted as a complete reply to the requirement for that item.

The requirement is subject to the provisions of 37 CFR 1.134, 1.135 and 1.136.

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9. Claims 56 – 59 rejected under **35 U.S.C. 103(a)** as being unpatentable over Oppenheim et al. (US Patent No. 5,837,247; of record, see entire document), as evidenced by Rasmussen et al. (FEBS Letters, 1996, 390: 109 – 112; of record, see entire document), in view of Grunfield et al. (US Patent No. 5,660,826, of record, see entire document).

Given the absence of additional rebuttal to the outstanding rejections of record (mailed 11/03/2003) in applicant's amendment (filed 02/09/2005), the rejection is maintained for the reasons of record.

The rejection of record is incorporated by reference herein as if reiterated in full.

10. Conclusion: no claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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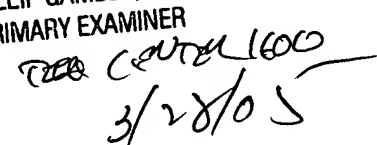
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI

Patent Examiner

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March 24, 2005


PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER

3/28/05